REMARKS

Claims 38 - 63 are in the application.

Applicant gratefully notes that the claim objections entered in the prior Examiner's Action dated June 16, 2008 have been withdrawn in response to applicant's amendment of November 13, 2008, as have the rejection entered under 35 U.S.C. 112, second paragraph, and the rejection entered under 35 U.S.C. 102(b) over Paris (U.S. Patent 6,331,205).

Applicant also gratefully notes that the drawing filed on June 15, 2005 have been accepted by the Examiner.

The claims have been amended to more particularly point out and distinctly claim applicant's invention. Independent claim 37 has been cancelled and new independent claim 63 substituted therefore. Claim 38 has been amended to limit the thickening agent to a smaller Markush group, and other dependent claims have been amended in the interest of further clarification. The amended claims are fully supported by the application as filed and present no new matter.

In particular:

a) *a dissolution step under mixing and cold conditions, of thickening agents having an instant gelatinizing property upon contact with complexing agent solutions in aqueous or hydroalcoholic medium buffered or not*:

is described :

- page 15 : "The mass is prepared, in majority of cases, under cold conditions
- page 4 and 5 :
    - ° "the thickening agents that exhibit the unique property of gelatinizing instantly upon contact with complexing solutions"
    - ° "certain substances of natural origin have a property of gelatinizing instantly upon contact with certain aqueous and/or hydroalcoholic solutions having a greater or lesser concentration of ions"

- page 16 : “the mixers used for production of this mass are conventional, of the kneader/mixer type.”
- page 10 :
    - “Depending on the thickening agent that is utilized, the dissolution medium can be aqueous or hydroalcoholic”
    - “The aqueous phase can be buffered, depending on the thickening agent used”

b) a solubilization step under mixing and cold or hot conditions, of additives

is described :

- page 15 “heating may be necessary in order to accelerate hydration or solubilization of the thickening agents and of certain other additives”
- page 20 : “The temperature of the preparation is gradually raised to 90°C to facilitate hydration of the hydroxypropyl starch upon its introduction into the medium

c) a vacuum degassing step to eliminate the air from the viscous mass

is described:

- page 16 : “Once the mass has been produced, it undergoes a conventional vacuum degassing step to eliminate air, which is capable of forming bubbles during production of the films”
- page 21 : “ After degassing of the preparation, it is….”
- page 20 : “The solutions thus produced have a viscosity when cold of between 200 millipascals and 1,000,000 millipascals…..

d) a transfer step of the viscous mass to the film formation system under 50°C temperature

is described:

- page 16 : “The degassed mass is transferred to the film formation systems either by simple gravity or under pressure, ;;;”

- page 21 : " After degassing of the preparation, it is transferred to encapsulation machines at a minimum temperature of 50°C.

e) a film formation step on drum systems around 10-15°C temperature

is described:

- page 14 : "From these solutions, films can be generated having a thickness on the order of 0.5 mm to 4.0 mm at the time of casting
- page 21: " by simple gravity or by pressure, formation of the following occurs (depending on the film production method):

" a deposit of mass on the drums, whose temperatures is on the order of 10-15°C, or,

a thick, non gelatinized film upon emergence from the feed opening between two cylinders, whose temperatures is on the order of 10-15°C"

f) an instantaneous gelatinization step of the viscous films by spraying or dipping, or both them in the complexing agent solutions

is described:

- page 16 : "as soon as the film has been formed, it is brought into contact with the complexing solution; This contact can be obtained by:

immersion

spraying; or

spraying/immersion.

Depending on the material employed to produce the films, immersion and/or spraying can be done simultaneously on both surfaces to the film, or alternatively by spontaneous detachment of the gelatinized film

g) a drying step of the gelatinized films through a air stream having a temperature comprised between –10°C to 70°C

is described:

- page 17 ; " the gelatinized film thus formed can be dried in an air stream whose temperature can vary from -10°C to 70°C during the process to transferring it toward the "encapsulation" section machine"
- page 21 : " the resulting film undergoes drying in an air stream whose temperature is controlled between +4°C and 30°C"

Written Description Rejection

Claims 37-62 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This rejection is respectfully traversed as applicable to the amended claims, and reconsideration and withdrawal of the rejection are respectfully requested.

The Examiner states that the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In particular, the Examiner states that with respect to claim 37, process steps (a)-(d) do not appear to be fully supported by the application as originally filed, inviting comparison between pages 6, 15-17, 20, and 21 of the specification, as well as original claims 32-36, with claim 37.

Applicant respectfully disagrees with the Examiner's rejection of the claims based on the written description requirement. The invention claimed in amended claims 36 et al. is fully described by the specification as filed, and fully meets the requirements of 35 U.S.C. 112, first paragraph.

Indeed:

"Claim 38. A process for manufacturing films for soft capsules according to claim 37, wherein the at least one thickening agent is selected from the group consisting of

arabic gums and their derivatives, lambda carrageenan, pullulan gums and their derivatives."

is supported by the description page 7 to 10.

"Claim 39. A process for manufacturing films for soft capsules according to claim 37, wherein the concentration of at least one thickening agent is between 2% and 80% by weight, relative to the final weight of the preparation."

is supported by the description page 9.

"Claim 40. A process for manufacturing films for soft capsules according to claim 37, the encapsulated mass comprising a blend of two or more thickening agents."

is supported by the description page 10.

"Claim 41. A process for manufacturing films for soft capsules according to claim 37, wherein the dissolution medium is a hydroalcoholic medium, and the proportion of the alcoholic for thickening agent dissolution in the hydro alcoholic medium varies from 10% to 90% by weight, relative to the total weight of the dissolution medium."

is supported by the description page 10.

"Claim 42. A process for manufacturing films for soft capsules according to claim 37, the dissolution medium further comprising at least one sodium or potassium salt to increase solubilization of the at least one thickening agent."

is supported by the description page 10.

"Claim 43. A process for manufacturing films for soft capsules according to claim 42, wherein the proportion of the sodium or potassium salt varies from 0 to 50% by weight, relative to the final weight of the preparation."

is supported by the description page 10.

"Claim 44. A process for manufacturing films for soft capsules according to claim 37, the dissolution medium having an aqueous phase, wherein the pH of the aqueous phase of thickening agent dissolution medium varies from 2 to 12."

is supported by the description page 10.

"Claim 45. A process for manufacturing films for soft capsules according to claim 37, the dissolution medium having an aqueous phase, wherein the pH of the aqueous phase is controlled with a buffered solution selected from the group consisting of hydrochloric acid/sodium chloride, hydrochloric acid/potassium phthalate, hydrochloric acid/glycine, citric acid/citrates, citric acid/sodium hydroxide, lactic acid/lactate, monosodium phosphate/disodium phosphate, monopotassium phosphate/dipotassium phosphate, bicarbonate/carbonate and potassium diphthalate/hydrochloric acid."

is supported by the description page 11.

"Claim 46. A process for manufacturing films for soft capsules according to claim 37, the encapsulating mass further comprising at least one polyol plasticizer selected from the group consisting of glycerol, sorbitol, maltodextrins, dextrose, manitol, xylitol, lactitol, propylene glycol, polyoxyethylene glycol 400 to 6000, natural and semi synthetic glycerides, and their derivatives."

is supported by the description page 11.

"Claim 47. A process for manufacturing films for soft capsules according to claim 46, wherein the proportion of the at least one polyol plasticizer varies from 0 to 50% by weight, relative to the total weight of the preparation."

is supported by the description page 12.

"Claim 48. A process for manufacturing films for soft capsules according to claim 37, the encapsulating mass further comprising at least one surfactant selected from the group consisting of ionic surfactants, non ionic surfactants, and amphoteric surfactants."

is supported by the description page 12-13.

"Claim 49. A process for manufacturing films for soft capsules according to claim 48, wherein the surfactant content of the encapsulated mass varies from 0 to 20%"

is supported by the description page 13.

"Claim 50. A process for manufacturing films for soft capsules according to claim 37, wherein the encapsulating mass further comprising at least one disintegrating agent, associated or not with surfactants, the at least one disintegrating agent being a soluble starch selected from the group consisting of potato starch, corn starch, rice starch, manioc starch, and wheat starch derivatives, the derivatives having been or not chemically or/and physically modified."

is supported by the description page 13.

"Claim 51. A process for manufacturing films for soft capsules according to claim 50, wherein the at least one disintegrating agent comprises between 0 and 50% by weight, relative to the total weight of the preparation."

is supported by the description page 13.

"Claim 52. A process for manufacturing films for soft capsules according to claim 37, wherein the concentration of solid material in the encapsulating mass is between 10% and 80% by weight, relative to the final of the composition."

is supported by the description page 14.

"Claim 53. A process for manufacturing films for soft capsules according to claim 37, wherein the film complexing agent solution is a saline solution of a mineral or organic acid, a hydroalcoholic solution, or a mixture of a saline solution of a mineral or organic acid and a hydroalcoholic solution."

is supported by the description page 14-15.

"Claim 54. A process for manufacturing films for soft capsules according to claim 53, the film complexing solution being a hydroalcoholic solution, wherein the

hydroalcoholic complexing solution contains ethanol, methanol, propanol, isopropanol, or butanol."

is supported by the description page 14.

"Claim 55. A process for manufacturing films for soft capsules according to claim 53, the film complexing agent solution being a hydroalcoholic solution, wherein the hydroalcoholic solution contains between 10% and 90% of alcohol by weight, relative to the final volume of the hydroalcoholic complexing solution."

is supported by the description page 14.

"Claim 56. A process for manufacturing films for soft capsules according to claim 53, the film complexing agent solution being a saline solution, wherein the saline complexing solution includes at least one ion selected from the group consisting of calcium ion, barium ion, titanium containing ions, zinc ion, aluminum containing ions, sulfur containing ions, and siliceous ions."

is supported by the description page 14.

"Claim 57. A process for manufacturing films for soft capsules according to claim 53, the film complexing agent solution being a saline solution, wherein the concentration of salt in the saline complexing solution agent ranges from 1% to the saturation of the solution."

is supported by the description page 15.

"Claim 58. A process for manufacturing films for soft capsules according to claim 37, wherein the ungelled film is contacted with the complexing solution by spraying complexing solution onto the ungelled film, dipping the ungelled film into the complexing solution, or both."

is supported by the description page 16.

"Claim 59. A process for manufacturing films for soft capsules according to claim 37, wherein the ungelled film is contacted with the complexing solution for between 10 seconds and 10 minutes."

is supported by the description page 15.

"Claim 60. A process for manufacturing films for soft capsules according to claim 37, further comprising drying the gelled film in an air stream at a temperature between –10 °C and +70 °C."

Is supported by the description page 17.

"Claim 61. A process for manufacturing films for soft capsules according to claim 37, further comprising sealing the gelled film under pressure and at the temperature between 50 °C and 100 °C."

is supported by the description page 18 and 21.

"Claim 62. A process for manufacturing films for soft capsules according to claim 37, further comprising encapsulating an aqueous and/or oily solution with the gelled film."

is supported by the description page 18.

Nevertheless, in the interest of expediting prosecution, applicant has amended the claims to substitute new independent claim 63 for independent claim 36. New independent claim 63 is believed to more closely track the exact language of the specification. Reconsideration and withdrawal of the rejection entered under 35 U.S.C. 112, first paragraph, are thus respectfully requested as applicable to the amended claims.

Provisional Double Patenting Rejection

Claims 37-62 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-40 of copending Application No. 10/511,260 ("the '260 application," published as U.S. Patent Publication

2005/0244489). Applicant again respectfully traverses this rejection and requests reconsideration and withdrawal of this provisional rejection.

The '260 application relates to sustained release from soft capsules, which depends upon the liquid content encapsulated in such soft capsules. The present application relates to a process for preparing the capsule shell, not the content *per se*. Thus, the presently claimed subject matter would not be obvious to one of ordinary skill in the art over the disclosure of the '260 application.

Moreover, the applicant of U.S. Patent Publication 2005/0244489 is the same as the present applicant: Laurence Paris.

Paris had already been issued U.S. Patent 6,331,205: "Aqueous viscous compositions, whether clear or not, for making soft or hard capsules, and method for making films for such capsules."

This patent protects the use of **IOTA** carrageenan for making soft capsule, **IOTA** carrageenan being a gelling agent like gelatin.

Therefore, U.S. Patent Publication 2005/0244489 refers to this patent in its claim 13, when it is written:

> "Liquid compositions according to claim 1, wherein the composition of the tunic of the capsule is constituted of gelatin or starches, or hydroxypropylmethylcellulose or carrageenans or of polymers of polyvinyl alcohol."

and not to the present application which has been filed 12 months after.

If this patent teaches about capsules made with carrageenan, it is not the aim of this U.S. Patent Publication 2005/0244489, the aim of this patent being sustained release compositions to be filled in any kind of soft or hard capsules.

In the claim 22 of the U.S. Patent Publication 2005/0244489 it is mentioned:

> "Liquid compositions according to claim 6, wherein the abovementioned hydrophilic additives belong to the class of celluloses and their derivatives, of starches and their derivatives, of polysaccharides such as guar, xanthan, tragacanth, and acacia gums,

carob, pectins, alginates, carrageenan, gellan gums, chitosan, polymers of vinylpyrrolidone."

Carrageenans, like the other polysaccharides cited in this claim, are used for modulating the release of the active substance contained in the matrix. Nothing in this patent publication teaches the use of carrageenan for making films and there is nothing about a complexing solution to gelatinize the carrageenan or the other polysaccharides included in the matrix.

Carrageenan, like the other polysaccharides, can be used in many applications. It is not because they have already been cited in one application, that it is the only application or way in which these ingredients can be used.

It is the most important characteristic of natural products like polysaccharides to be used in many applications with many different properties. Person skilled in art knows this very well.

Obviousness Rejections

Claims 37-62 stand finally rejected under 35 U.S.C. 103(a) as obvious over U.S. Patent 6,331,205 ("Paris"). This rejection is respectfully traversed, and reconsideration and withdrawal of the rejection are respectfully requested as applicable to the amended claims.

The Examiner states that Paris teaches a process for manufacturing gelatinized films for soft capsules (citing the Abstract). The Examiner notes that Paris teaches dissolving at least one thickening agent such as a carrageenan in an aqueous or hydroalcoholic dissolution medium to form a viscous encapsulating mass (citing col. 2, lines 42-55). The Examiner states "that a film complexing agent is provided which contains a film complexing agent," (sic) and the complexing solution is contacted with the viscous encapsulating mass to form a gelled material (citing col. 2, line 52, through col. 3, line 67). The Examiner further states that the gelled film is used to make soft capsules (citing col. 5, lines 44-48).

The Examiner admits that Paris does not appear to teach the steps of forming an ungelled film from the encapsulating mass or contacting with the ungelled film with the complexing solution to "instantly" gel the ungelled film.

Nevertheless, the Examiner contends that the viscous encapsulating mass would have intrinsically formed a film at the interface of the container wall, and when the complexing agent was added that film would have gelled.

The Examiner states that term "instantly" also is a relative term without clear-cut upper and lower limits. The Examiner explains that present claim 59 appears to indicate that "instantly" includes a time between 10 seconds and 10 minutes.

The Examiner concludes that it would have been obvious for the process of manufacturing gelatinized film, as taught by Paris, to have the steps of forming an ungelled film followed by contacting that film with a complexing solution to "instantly" form a gel film, because Paris teaches the steps of mixing the ungelled mass and the complexing solution to form a soft capsule.

The Examiner notes that the term "instantly" appears to include times as long as 10 minutes.

In response, applicant contends that the Examiner has not carried his burden of established a *prima facie* case of obviousness as the rejection includes several factual errors which result in a legally erroneous conclusion.

Indeed if (col. 2, lines 42-55) refers to the U.S. Patent 6,331,205, Paris doesn't teach that which the examiner would want him to teach.

Col. 2, lines 42-55 mentioned:

> "The Iota (ί) carrageenans are, in the concept of the present invention, used on their own, without the addition of another gelling agent, contrary to carrageenans used in the prior art of manufacturing films for hard or soft capsules. The concentration in carrageenan will preferably be higher than 5% of the medium with a maximum limit set to 80%. Advantageously, the volume of dissolution of the

carrageenan can be water as well as a polyhydric alcohol blend of which the proportion in alcohol will vary between 0 and 60%.

The medium must be buffered so as to avoid a deterioration of the carrageenan in time under the effect of heat. In effect, in buffer medium and during a twenty-four hour period, a diminution of the viscosity of the medium through progressive hydrolysis of the carrageenans freeing acids radicals in the medium can be seen."

Nothing in this paragraph speaks about thickening agent. A person skilled in art knows perfectly that **IOTA** carrageenans are gelling agents and **LAMBDA** carrageenans are thickening agents (col. 2, lines 40-42):

"The Lambda (λ) shape presents thickening characteristics but not gelling ones"

Combined with the content of col. 1, lines 52 -57:

"The aim of the present invention is to make the substitution of film for hard and soft capsules with a shell based from product of wholly vegetal origin which is much used in the food industry field, the carrageenans used pure as the one and single gelling agent of the composition of the shell with a concentration higher than 5% in solution in the medium."

It appears for the person skilled in art, that lambda carrageenan is not the best carrageenan for making hard and soft capsules in U.S. Patent 6,331,205: "used pure as the one and **single gelling agent.**"

Lambda carrageenan possesses different physical properties from iota carrageenan, but some properties are the same, specifically, solubilization. So, Iota and lambda can be dissolved in the medium giving a viscous solution. But by heating these solutions one is going to give a solid phase by cooling (iota carrageenan) and the other will still stay liquid by cooling (lambda carrageenan). In one case it will be easy to obtain film by a simple cooling of hot solutions on cold drums (iota carrageenan) in the other case no (lambda carrageenan).

Moreover in (col. 2, line 52, through col. 3, line 67) it is mentioned :

"The medium must be buffered so as to avoid a deterioration of the carrageenans in time under the effect of heat. In effect, in buffer medium and during a twenty-four hour period, a diminution of the viscosity of the medium through progressive hydrolysis of the carrageenans freeing acids radicals in the medium can be seen. This reaction is blocked when medium is buffered. The pH value can vary between 5 and 12. Different buffering systems can be used:

citrate buffer : citric acid/citrates

phosphates buffer : sodium phosphate or potassium phosphate,

phthalate buffer : potassium diphthalate/hydrochloric acid,

borate buffer : boric acid/sodium borate

carbonate buffer : bicarbonate/carbonate.

The agents favorising the dissolution of carrageenans belong to the alkaline class and the alkaline earth : sodium, calcium, potassium ,etc…. and are introduced in the medium in the shape of :

Salts of hydrochloric, sulfuric, nitric, phosphoric, and citric acids and derived acids;

Hydroxides

The proportion of alkaline ions and alkaline earths that can be introduced in the medium varies between 0 and 50% in relation to the final volume of solution.

The elasticity of the films is obtained by the use of plasticizers which belong to the polyoxyls class: glycerol, sorbitol, maltodextrins, dextrose, mannitol, xylitol, polyoxyethylene glycol 400 to 6000, natural glycerides and hemisynthetics and their derivates, etc.

The quantity of these substances introduced in the solution of carrageenan is such that the coefficient of elasticity of the film can vary from 1 to 5 (1 to 5 times the initial length). The proportion of these substances that can be introduced in the medium varies between 0 and 30% in relation to the final volume of the solution.

The obtaining of a gradual disintegration time defined from the film is controlled by the introduction of tensio-actives in the medium, combined or not to substances presenting a power of disintegration. The tensio-actives used in the present invention can be non ionics. These are:

sorbitane esters: polysorbates, spans, tweens, etc..

fatty acids polyethoxyls: stearate of PEG 8 to stearate of PEG 100;

fatty polyethoxyled alcohols: blend of ethyl of monolaurate of PEG having from 4 to 23 oxyethylen groups on the polyoxyethylenic chain, etc.

glycol esters: stearate of methylglycol

glycerol esters: monostearate of glycerol, etc.

esters of PEG;

saccharose esters;

ethyls of fatty alcohol and of PEG : Brij;

ethyls of alkyl phenol and of PEG;

tension-actives presenting an amide function such as :

monoethanolamide of fatty acids of coprah, of lauric acid, etc..

diethanolamide of myristic acid, of lauric acid, et..

mono-isopropanolamine of lauric acid

ionics. Which are:

derived sulfates : the laurylsulfate of sodium and its derivatives;

derived sulfones dodecylsulfosuccinate of sodium and its derivatives;

quaternary ammoniums : cetyltrimethyalmmonium chloride, laurylpyridinium, distearyldimethylammonium, etc.

amphoterics : ammonium betaine of alkyldimethyl of coprah, derived from amids of fatty acid with betainic structure, lauryl-b-iminodipropionic acid and its derivatives, lauryl-myristyl–b-aminopropionic acid and its derivatives, etc..

The quantity of these substances introduced in the carrageenans solution is such that the disintegrating time can vary from 3 minutes to 8 hours. The quantities can vary from 0% to 20% in relation to the final volume of the solution. These tensio-actives can be combined with substances to improve the disintegration time, like wheat, rice, corn, manioc starch whether they have or not been subject to modifications. The final quantities used can vary from 0 to 20% in the relation to the final volume of solution."

Nothing in U.S. Patent 6,331,205 speaks to a complexing solution for gelatinizing the encapsulating mass. On the contrary, the additives referenced by the Examiner have entirely different functions:

(a) Alkaline and alkaline earth ions enhance the solubility of iota carrageenan in the medium.

(b) The buffer solution stabilizes the solution under hot conditions.

(c) Plasticizers increase the elasticity of the film.

(d) Tensio-actives and starches increase the disintegration time of the film.

These additives can also be used for the present application to give the same properties of film as those of ordinary skill in the art know that it is necessary to:

(a) stabilize the pH of the solution to avoid hydrolysis of ingredients such as specifically, carrageenans such as iota and lambda carrageenan, that might otherwise be experienced under inordinately acidic or basic conditions;

(b) increase the elasticity of films for encapsulation, since if the capsules are not sufficiently elastic they may explode from the pressure applied during the filling process; and

(c) increase the disintegrating time, since if the capsules will not disintegrate, the active ingredient will not be released as desired.

These considerations are applicable whatever the material used to manufacture the capsule. However, these additional ingredients are secondary to the process steps used to manufacture the films, namely, heating and cooling for iota carrageenan compositions, and the complexing process for lambda carrageenan disclosed and claimed in the present application. The additional ingredients contribute to obtaining a perfect capsule, but are not essential to the presently claimed process.

The Examiner construes "instantly" to be a relative term with no clear-cut upper and lower limits. Indeed, the gelatinization process is something which can takes time depending on the composition of the encapsulated mass. The gelatinization process occurs instantly at the interface between the liquid complexing agent solution and the film surface, but it may require some time for the complexing agent to diffuse through the film and continue to gelatinize the mass. Thus, claim 59 provides for up to 10 minutes for the complexing agent to diffuse into the ungelled film in order to instantly gel the film under the surface in contact with the complexing solution. Thus, the Examiner's construction that "instantly" can mean up to 10 minutes is unsupported by the disclosure.

The Examiner cites Paris at length with respect to claims 38-62. However, the parallel disclosures in the present application and in Paris reflect the fact that the objective (making non-gelatin capsules) is the same. However, different processes and key materials are used in each. In one case (Paris) the key material is **IOTA** carrageenan, a gelling agent. To use the material we have to:

(a) Dissolve iota carrageenan in aqueous medium giving an aqueous viscous liquid.

(b) Heat the solution until 90°C to develop the gelatinization properties of iota carrageenan. This step is a *compulsory* step.

(c) Cast viscous films on drums having a temperature around 10 – 12°C for solidifying by gelatinization the aqueous viscous liquid, giving a three dimensional structure.

On the other hand in the present application, where the key material is **LAMBDA** carrageenan, thickening agent, one must:

(a) Dissolve lambda carrageenan in aqueous medium giving an aqueous viscous liquid.

(b) Cast viscous films (e.g. on drums);

(c) Spray a complexing solution for solidifying by chemical gelatinization the aqueous viscous liquid, giving a three-dimensional structure. This step is a *critical* step

The prior art other than Paris teaches processes for making soft capsules using material other than carrageenan, like thermoplastic starches patented by the Swiss Caps Company. Here too, additives like preservatives, coloring agents, disintegration agents, plasticizers are disclosed in these applications.

What is important in the application is the principle employed, and not the various additives. In the present case, the principle is making soft capsules using thickening agents, in contrast to prior art processes where gelling agents or thermoplastic ingredients are employed. The present process used to reach the target, soft capsules, is totally different:

In the case of gelling agents, gelatinization is achieved by thermo effect.

In the case of thermoplastic agents, gelatinization is achieved by a cracking process.

In the present case, the use of thickening agents, gelatinization is achieved by a chemical process, namely a chemical complexation process.

Our comments on each remark made by the Examiner are compiled in tables below:

Teaching of Paris' US6331205	Comments
Aqueous viscous composition is taught for the manufacture of soft capsules. Abstract Gelatinization occurs with the addition of thickening agents. Col. 1, line 50, through col. 2, line 10. Elasticity is controlled with plasticizers. Col. 3, lines 5-15 Disintegration is controlled with surfactants or polysaccharides. Col. 3, lines 20-67 Preservation is controlled with preservatives. Col. 4, lines 1-10. The soft capsules may contain oily and/or aqueous solution. Col. 4, lines 25 – 50	Whatever is the gelling agent or the thickening agent set during the film casting, it is necessary to have a viscous aqueous liquid composition. It is that the soft capsule manufacture teaches. In col. 1, line 50, through col. 2, line 10., nothing teaches the use of thickening agents as "gelling agent". It is written : *"The aim of the present invention is to make the substitution of film for hard and soft capsules with a shell based from a product of wholly vegetal origin which is much used in the food industry field, the carrageenan used pure* ***as the one and single gelling agent of the composition of the shell*** *with a concentration higher than 5% in solution in the medium".* Few lines after, it is written : *"**The Iota carrageenan type** preferably adopted in the present invention does not present the syneresis phenomenon and leads to films presenting a certain elasticity necessary to the manufacturing of soft capsules.* Nothing speaks about lambda carrageenan in this sentence. Again line 64 it is written : *"the addition of a certain number of substances leads to…..",* No description of these substances is made there Whatever is the gelling agent, gelatin or iota carrageenan (patent US6331205), or the thickening agent, it is always necessary to add plasticizers Same comments as for plasticizers. (see above) Same comments as for plasticizers. (see above) Like patent US6331205, this application is to manufacture soft capsules. So its purpose is to manufacture films for encapsulated oily or aqueous solutions.
The thickening agents include lambda carrageenan. Col. 2, lines 25 and 26	Line 25 and 26 of Col. 2 only cites *"lambda carrageenan"*, without telling if they are gelling or thickening agents. In this column, line 21 to 40, we describe any kind of carrageenan we can find on the market, and the properties of type of carrageenan. But nothing in this column says that lambda carrageenan are used as thickening agent for making films for soft

	capsules. More than this line 42, it is written : “ *the Iota carrageenan are, in the concept of the present invention, used on their own without the addition of another gelling agent, contrary to carrageenan used in the prior Art of manufacturing films for hard and soft capsules”.*

Teaching of Paris' US6331205	Comments
The thickening agent is > 5% in the medium. Col. 1, lines 55 – 60	In col. 1, lines 55 – 60, instead of thickening agent it is written "single *Gelling agent"* which is not the same as thickening agent. More than this, the carrageenan described in this column is iota carrageenan and not lambda carrageenan.
Prior art taught using additional gelling, i.e., thickening agent. Col. 2, lines 40 – 50	In this column it is written : " *the Iota carrageenan are, in the concept of the present invention, used on their own without the addition of another gelling agent, contrary to carrageenan used in the prior Art of manufacturing films for hard and soft capsules".* The prior Art describes combination of gelatin/iota carrageenan, iota carrageenan/kappa carrageenan (kappa carrageenan is another gelling agent), iota carrageenan/galactomananes, etc…., so two gelling agent, only. Nothing in the prior Art describes the used of a thickening agents for making soft capsules, specifically the used of lambda carrageenan for making soft capsules combined to another thickening agent.
The amount of the thickening agent may be > 5% to 80%. Col. 2, lines 45 – 55	It is not a thickening agent used in Paris' US6331205, but a gelling agent.
The amount of alcohol may be between 0 and 60%. Col. 2, lines 48 – 51	Whatever is the carrageenan, iota or lambda, the method for dissolving the carrageenan is the same, indeed. But at the end of mass manufacturing under hot conditions, one is going to gel by cooling, iota carrageenan mass, the other will be still pasty, lambda carrageenan, even under cold conditions. Only the action of ions will set the mass during its casting on the drums.
Solubilization agents include alkali and alkaline earth ions, in the amount of 0 – 50 vol. %. Col. 2, line 66, through col. 3, line 10.	As it is mentioned in the description of this application, the alkali or alkaline-earth ions used to increase the solubilization of the lambda carrageenan, are sodium and potassium, only. Page 4, col. 4 [0072, 0073,0074]. But, like above, it is not because we use the same ions to increase the solubility of lambda carrageenan that this application is the same as Paris' US6331205. Indeed using sodium or potassium ions for increasing the solubility of iota or lambda carrageenan have no influence on the setting mass of the carrageenan. The lambda carrageenan mass will still be pasty after cooling it, and iota carrageenan will gel. .

Teaching of Paris' US6331205	Comments
Solubilization agents include alkali and alkaline earth ions in the amount of 1-50 vol. %. Col. 3, lines 5-10.	Even if we have the same alkali or alkaline earth concentration for increasing the solubilisation of carrageenan, the aims of the two patents are totally different : - iota carrageenan give gelled films by cooling the mass - lambda carrageenan give pasty films by cooling, gelled by spraying a complexing solution onto them.
The alkaline or alkaline earth ion is introduced in the form of hydroxide or a salt of hydrochloric, sulfuric, nitric, phosphoric, or citric acid, and derivatives. Col. 3, line 1-5.	Like above, even if we have the same salt of alkali and alkaline–earth ions for increasing the solubilisation of carrageenan, the aims of the two patents are totally different : - iota carrageenan give gelled films by cooling the mass - lambda carrageenan give pasty films by cooling, but gelled following a complexing solution spraying onto them.
The pH can vary between 5 and 12, col. 2, lines 55-60	Like above, even if we have the same pH of the carrageenan dissolution medium, the aims of the two patents are totally different : - iota carrageenan give gelled films by cooling the mass - lambda carrageenan give pasty films by cooling, but gelled following a complexing solution spraying onto them.
Various buffering systems, including the citrate, phosphate, phthalate, and carbonate systems, are taught. Col. 2, lines 50-65	Same comments as above
Plasticizing agents such as glycerol, etc…. are taught at Col. 3, lines 9-15	Whatever the film forming agent for soft capsules is, gelatin, iota carrageenan, agar-agar, etc…., still plasticizing agents are needed to increase the elasticity of the films. So even if we use the same plasticizing agents, the aims of the two patents are totally different : - iota carrageenan give gelled films by cooling the mass - lambda carrageenan give pasty films by cooling, but gelled following a complexing solution spraying onto them.
The plasticizing agent may be present in the amount of 0-30 vol. %. Col. 3, lines 15-20	Same comments as above
Ionic, nonionic, and amphoteric surfactants are taught at Col. 3, lines	Whatever the film forming agent for soft capsules is, gelatin, iota carrageenan, agar-agar, etc….

25-60	surfactants can be used to increase the disintegration of the soft capsules shells. So even if we use the same surfactants, the aims of the two patents are totally different : - iota carrageenan give gelled films by cooling the mass - lambda carrageenan give pasty films by cooling, but gelled following a complexing solution spraying onto them.
The amount of surfactant can be 0-20 vol. %. Col. 3, lines 60-65.	Same comments as above

Teaching of Paris' US6331205	Comments
Starch-type disintegrating agents can be added as well. Col. 3, line 60-67	Same comments as above
Corn, rice, manioc, wheat starches are taught at Col. 3, line 60-67	Same comments as above
Amounts of 0-20% vol. % are taught at Col. 3, lines 65-67	Same comments as above
Preservatives and/or coloring adjuvants are taught. Col. 4, line 1-3	Same comments as above
Preservatives may be present in the amount of 0-10 vol. %. Col. 4, lines 1-5	Same comments as above
The coloring agent can be 0.01- 5 vol. %. Col. 4, lines 5-10	Same comments as above
Opaque agents can be 0-10 vol. %. Col. 4, lines 5-10.	Same comments as above
Saline solutions, i.e., acid salts, and hydro alcoholic solution are taught at Col. 2, line 66 through Col. 3, line 10.	In Paris' US6331205 the saline solutions are used to increase the solubility of iota carrageenan, not for gelling film of iota carrageenan. Previously, it has been made the distinction of what kind of ions can be used in this application to increase carrageenan solubilization : sodium and potassium, only. So in this application two kind of ions are used : - sodium and potassium for increasing the solubility of lambda carrageenan, like for iota carrageenan - calcium, barium, titanium, zinc, aluminum, sulfur and silicates (see claim 26) for gelling the film after its casting on the drum. These two kind of ions are clearly identified and described in this application
The amounts of polyhydric alcohol is 0-60%. Col. 2, lines 48-51	Like previously, alcohols or polyhydric alcohols used in Paris' US6331205 are totally different from those used for complexing the lambda carrageenan film. In Paris' US6331205, the alcohols used is for the solubilization of carrageenan as it is mentioned lines 48-49 : *"Advantageously, the volume of dissolution f the carrageenan can water as well as a polyhydric alcohol blend".* Nothing, there, teaches the used of alcohol or polyhydric alcohol as "complexing solution" for gelling lambda carrageenan films.

Teaching of Paris' US6331205	Comments
Salts, hydroxides, carbonates and alkaline earth ions are taught at Col. 2, line 52 through Col. 3, line 9.	Like previously, salts cited in Paris' US6331205, have not the same target of those described in claim 53. As it is said previously, ions described in Paris' US6331205, is for increasing solubilization of iota carrageenan and not for gelling them. Moreover, we already said that we have identified two kind of ions used in this application : - sodium and potassium for increasing the solubility of lambda carrageenan, like for iota carrageenan - calcium, barium, titanium, zinc, aluminum, sulfur and silica (see claim 53) for gelling the film after its casting on the drum. These two kind of ions are clearly identified and described in this application
The amount of salts, hydroxides, and carbonates may be 0-50 vol. and the pH can be range from 5 to 12. Col. 2, line 55, through Col. 3, line 10	In Paris' US6331205, the salts cited Col. 2 line 55, through Col. 3, line 10 are dissolved in the carrageenan dissolution medium. In the application 10/539,100, the salts are dissolved in a solution apart from this of carrageenan and this solution is sprayed onto lambda carrageenan films to obtain their gelification. So, even if it these salts are already described in Paris' US6331205, for some of them, they are not used in the same conditions as Paris' US6331205, : - dissolved in a separate solution from carrageenan solution - and sprayed on lambda carrageenan films in the purpose of gelling these one.
The solution is transferred to the machines for processing, i.e., immersion. Col. 5, lines 40-50	Nothing in Paris' US6331205, teaches about "spraying" or "immersion" during the soft capsule process. In Scherer process, as it is indicated in Paris' US6331205, the iota carrageenan mass is cast on drums having a temperature around 12°C. Due to this cold temperature, the iota carrageenan instantaneously gels, like gelatin. In the present application, lambda carrageenan mass in contact with the drum having a temperature of 12°C does not gel. The gelification of the film is obtained by spraying the complexing solution onto the drum or by dipping a part of the drum in the complexing solution. Therefore the two processes for making soft capsules using iota carrageenan or lambda carrageenan are totally different.
Lubricants are taught at Col. 4, line 35-26	Whatever the gelled film is, gelatin, iota carrageenan, agar agar, it is necessary to use

	lubricants to avoid that the films stick on the drum. So even if we use the same lubricants, the aims of the two patents are totally different : - iota carrageenan give gelled films by cooling the mass - lambda carrageenan gives pasty films by cooling, but gelled following a complexing solution spraying onto them.

Teaching of Paris' US6331205	Comments
The soft capsules may contain oily and/or aqueous solutions. Col. 4, lines 25-50	Here also whatever the gelled film is, gelatin, iota carrageenan, etc…., the aim of this application is not to protect the content of the capsules but the process to obtain them. In this application thickening agents are used instead of gelling agents. The gelification of the thickening agent is obtained by spraying specific solutions having the property to complex the thickening agent, like calcium salts and lambda carrageenan giving a tri dimensional solid structure.
Processing steps are taught at Col. 5, lines 30-55	Whatever gelling agents used to manufacture films is, gelatin, iota carrageenan, the process for manufacturing the mass is the same: - solubilization of the gelling agent or thickening agent - addition of plasticizers, coloring agents, disintegrating agents, etc…. So in this application it is not how to manufacture the mass for the film, but how to gel a pasty film coming from a thickening agent mass.
Temperature of 70-100°C are taught at Col. 5.,lines 50-55	The temperature cited lines 50-55 is the temperature of the dies for sealing the soft capsules, but not for manufacturing the mass.
The solution is transferred to the machines for processing, i.e.; immersion. Col. 5, lines 40-50	The person skilled in Art knows that, in any kind of process for manufacturing soft capsules (gelatin, or iota carrageenan) there is no dipping system for jellifying the film coming from the tank, where the mass is stocked, to the drum, and from the drum to the dies for sealing the soft capsules. What it is described in this application, is the immersion of the film fixed onto the drum in the complexing solution. Nothing like this is described in Paris' US6331205 and in any others patents speaking about soft capsules manufacturing.
Drying occurs at –4°C. Col. 5, lines 45-50	Whatever the process is to obtain films, the method to drying it is the same. But here it is not the method for drying a film but the method for gelatinized a film from a pasty mass like lambda carrageenan mass, which is the most important.
Temperatures of 70-100°C are taught at col. 5, limes 50-55.	Here also, whatever the process is to obtain films, the method to seal the soft capsules still is the same : hot wedge having a temperature around 50°- 100°C. This temperature depends on the gelling agent used : gelatin (50-60°C), iota carrageenan (70-80°C). But here it is not the method for sealing soft

	capsules which is the most important but the method for gelatinized a film from a pasty mass like lambda carrageenan mass
A vacuum is applied. Col. 5, line 35-40.	Any pasty mass, during its mixing is submitted to a degassing step to avoid bubbles. Therefore whatever the pasty mass is, degassing process is not the most important part of this application. It is how to gel a pasty mass to obtain film having a solid tri dimensional structure.

Teaching of Paris' US6331205	Comments
Temperatures of 70-100°C are taught at col. 5, lines 50-55.	Here also, whatever the process is to obtain films, the method to seal the soft capsules still is the same : hot wedge having a temperature around 50°- 100°C. This temperature depends on the gelling agent used : gelatin (50-60°C), iota carrageenan (70-80°C). But here it is not the method for sealing soft capsules which is the most important but the method for gelatinized a film from a pasty mass like lambda carrageenan mass
A vacuum is applied. Col. 5, line 35-40.	Any pasty mass, during its mixing is submitted to a degassing step to avoid bubbles. Therefore whatever the pasty mass is, degassing process is not the most important part of this application. It is how to gel a pasty mass to obtain film having a solid tri dimensional structure.
The viscous mass is still liquid, so it flows by "simple gravity". Col. 5, lines 40-50.	Depending on what we add in the mass, this one can be enough liquid to flow by itself, like gelatin, or can have a high viscosity needing an endless screws or a press, like carrageenan. But here, too, it is not how to transfer the mass from the tank to the drum which the important in this application, but how to gel a pasty mass obtaining films having a solid tri dimensional structure.

With respect to claim 54, the Examiner admits that Paris does not appear to teach the C1-4 alcohols claimed, but notes that Paris teaches polyhydric alcohols and dissolution agents, and thus concludes that lower MW alcohols such as ethanol would have been an obvious variation because they are water soluble and have a hydroxy unit, and such lower MW alcohols also would have been well know dissolution agents.

The claim 54 indicates what kind of alcohols can be used for complexing the film of lambda carrageenan and not what kind of alcohols can be used to dissolve carrageenan for manufacturing the viscous mass, as it is described in US Patent 6,331,205. This is clearly mentioned in the claim 54

"Claim 5. A process for manufacturing films for soft capsules according to claim 53, ***the film complexing solution being a hydroalcoholic solution****,* ***wherein the hydroalcoholic complexing solution*** *contains ethanol, methanol, propanol, isopropanol, or butanol." (emphasis added)*

Therefore there is no ambiguity between the U.S. Patent 6,331,205 and the present application.

Regarding claim 59, the Examiner admits that Paris does not specify a gelatinization time of 10 seconds to 10 minutes, but nonetheless contends that Paris teaches processing until a viscous mass is formed, citing col. 5, lines 30-45. The Examiner infers that gelatinization would intrinsically occur within that period, at the time the viscous mass formed. This is not correct.

Indeed, how long time the viscous mass takes to become solid, is not the aim the applications, U.S. Patent 6,331,205 or the present one. The aim of the applications is how we obtain a gelled mass:

- US Patent 6,331,205 : by heating and cooling the viscous mass
- Present application : by chemical reaction with viscous mass and some ions or alcohols in solution (complexing solutions)

By thermo effect, U.S. Patent 6,331,205, the gelatinization is instantly obtained on a cold plate having a temperature around 10°-12°C like drums described in any king of soft capsules process.

By complexing solutions the gelatinization is instantly produced by spraying or dipping.

Therefore there is no ambiguity between the U.S. Patent 6,331,205 and the present application due to the fact the process for obtaining a gelled mass is totally different.

Claims 37-62 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Paris in view of WO 01/007507 ("Scott"). This rejection is also respectfully traversed, and reconsideration and withdrawal of the rejection are respectfully requested as applicable to the amended claims.

The Examiner states that with respect to claim 38, Paris does not specifically teach the recited thickening agents other than the carrageenans, but Scott teaches those other thickening agents (citing p. 9, line 21, through p. 10, line 23) as well as the use of viscous aqueous liquids for making soft capsules (citing the Abstract).

The Examiner concludes that in view of the record as a whole, therefore, it would have been obvious to substitute the carrageenan taught by Paris with the other thickening agents taught by Scott because both references teach viscous aqueous compositions for making soft capsules and Scott further teaches that other thickening agents would work as well, citing *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007), for the proposition that "[t]he combination of familiar [components] according to known methods is likely to be obvious when it does no more than yield predictable results."

Despite the conclusion of the examiner, it clearly appears in Scott's application that manufacturing protected totally is different, and the ingredients used, too.

Indeed Scott in his application protects the manufacturing of hard capsules, first, secondary soft capsules.

The manufacturing of these hard capsules is based on using thickening agent, pullulan gum, but in combination with a setting agent to obtain a gelatinization by cooling the blend of these two compounds after heating it.

Therefore Scott does not protect the same process for manufacturing film from thickening agent. We are in the process of gelatinization by thermo effect.

This is clearly mentioned page 9, line 8-9 of Scott's application:

"Surprisingly we found that the addition of a very small amount of a setting system comprising hydrocolloids acting as a gelling agent"

In the application 10/539,100 it is clearly specified that the innovation does not include a blend of thickening agent and gelling agent like those of Scott, but only blends of thickening agents, page 5 :

"The films thus obtained, when cold, exhibit characteristics similar to a gelatin film, in particular with regard to thermo reversibility, elasticity, and disintegration time, by the addition or not of ingredients promoting such parameters. No gelatinizer such as gelatin, iota or kappa carrageenan, xanthane gum, etc, is used in combination with the aforesaid thickening substances to produce the requisite properties described above"

Moreover page 7, line 3 Scott indicates :

"*The cation containing salt in the composition serves to enhance the setting ability of the gelling agents*".

Even if Scott speaks about carrageenan in his patent, the carrageenan cited are kappa carrageenan which is a gelling agent giving brittle gels, compared with lambda carrageenan giving only pasty masses.

Likewise, Scott describes an aqueous viscous composition for hard capsules, which is totally different from those for soft capsules due to the fact that the manufacture processes are completely different between hard and soft capsules.

Even if Scott protects his compositions for soft capsules, too, a person skilled in art knows that making a gelled mass is not enough to produce soft capsules. Other parameters must be taken into account for manufacturing soft capsules, like thermoreversibility of the mass, the elasticity of the films etc. which are things which have not been studied by Scott in his application.

In conclusion Scott protects only one thickening agent : Pullulan.

he other ingredients protects by Scott are setting agents or more exactly gelling agents, ingredients which have never been protected in Paris application.

Moreover, the Examiner's statement that Scott also teaches the use of viscous aqueous liquids for making soft capsules (citing the Abstract) is simply not true.

Indeed, it is not because Scott protects a viscous aqueous liquid for making soft capsules in the abstract that it is possible. Nothing in his application teaches about physical properties required for making soft capsules, specifically the addition of plasticizers needed to obtain a good elasticity of the film.

All the other ingredients other than pullulan described by Scott are setting agents equal to gelling agent. Paris in his application has been very precise about the thickening agent selection made, page 4:

> "For that purpose, the viscous aqueous or hydroalcoholic liquid components, buffered or not intended for the production of films for the manufacture of soft capsules according to **the present invention are notable in that the gelatinization thereof is obtained extemporaneously starting with thickening agent that exhibits the unique properties of gelatinizing instantly upon contact with complexing solutions**, the elasticity of the films being obtained by introducing or not introducing a plasticizing agent, etc." (emphasis added)

No setting agents cited by Scott reacts like this.

Scott combines thickening agents (page 9, lines 22-30, page 10, lines 1-5) :

In a preferred embodiment of the present invention, the polysaccharides are selected from the group comprising alginates, agar gum, guar gum, locust bean gum (carob),

carrageenan, tara gum, gum arabic, ghatti gum, Khaya grandifolia gum, tragacanth gum, karaya gum, pectin, arabian (araban), xanthan, gellan, starch, Konjac mannan, galactomannan, funoran, and other exocellular polysaccharides. Preferred are exocellular polysaccharides.

Preferred exocellular polysaccharides for use in the present invention are selected from the group comprising xanthan, acetan, gellan, welan, rhamsan, furcelleran, succinoglycan, scleroglycan, schizophyllan, tamarind gum, curdlan, and dextran."

with setting systems (page 10, lines 11-14):

"In a further preferred embodiment of the present invention the hydrocolloids of the setting system are kappacarrageenan or gellan gum or combinations like xanthan with locust bean gum or xanthan with konjac mannan."
Among the setting systems mentioned above, the systems of kappa-carrageenan with cations and gellan gum with cations are specifically preferred. They produce high gel strength at low concentrations and have good compatibility with pullulan."

Any person skilled in art knows that "setting systems" are gelling agents, even mentioned by Scott himself (page 6, lines 29-30):

"The setting system is preferably composed of a gelling agent, such as said hydrocolloids or polysaccharides, and optionally salt and sequestering agent."

About Paris' arguments, the examiner considers that the answer: "present application relates to the composition of the capsules shell, not the content per se" it is not persuasive because present claim 62, which depends from present claim 37, also involves the content of the capsule".

In the new claims proposed, claim 62 has been deleted and not replaced.
Indeed if we withdraw claim 62 from the rest of the claims, this is not going to modify the aim of the patent which is to obtain gelled film by spraying complexing solutions onto a viscous mass of thickening agent in the purpose to gel the mass.

Moreover responding to applicant's argument that the carrageenan in Paris do not function as gelling agents, the Examiner implicitly admits as much, but responds that the

present claims have the term "comprising" which does not exclude those gelling agents. This proves too much. "Comprising" appeared twice in now-cancelled claim 37: First, "comprising" appears in the preamble where it "does not exclude" additional process steps. Second, it appears in step (c) where it "does not exclude" components other than a film complexing agent from the film complexing solution. Presumably, by the Examiner's reasoning, a gelling agent could be included in the film complexing solution. However, this scenario just emphasizes the Examiner's inability to make out a prima facie case. Following the Examiner's logic, the film complexing solution would contain both a gelling agent and a film complexing agent. However, there is nothing in the cited art that would teach, suggest or motivate one of ordinary skill in the art to include a film complexing agent when a gelling agent is used, or that a film complexing agent could be substituted for the gelling agent.

In U.S. Patent 6,331,205, Paris discloses a process for making a film for manufacturing soft gelled capsules. A hydrocolloidal solution prepared by dissolving a iota carrageenan in a buffered solution (col. 5, lines 31-43), and optionally dispersing an opaquing agent. The carrageenan solution is then simply "transferred towards the machines for manufacturing gelled films or soft capsules where the storing temperature is maintained between 80º C and 90º C." (col. 5, lines 44-47). Presumably, the machines cool the carrageenan solution to gel the carrageenan and to "produce a more or less breakable film" (col. 1, lines 57-60).

Further, there is nothing in U.S. Patent 6,331,205 which would teach or suggest the presently claimed invention to one of ordinary skill in the art at the time the invention was made.

A claimed invention is not patentable if its subject matter would have been obvious to a person of ordinary skill in the art. 35 U.S.C. § 103(a); *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007). Facts which are relevant to a determination of obviousness include (1) the scope and content of the prior, (2) any differences between the claimed invention and

the prior art, (3) the level of ordinary skill in the art and (4) relevant objective evidence of nonobviousness. *KSR Int'l Co.*, 127 S. Ct. at 1734. "'A prima facie case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art.'" *In re Bell*, 991 F.2d 781, 783 (Fed. Cir. 1993), *quoting In re Rinehart*, 531 F.2d 1048, 1051 (CCPA 1976). Further, "[i]f an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious." *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1696 (Fed. Cir. 1988).

In U.S. Patent 6,331,205, Paris simply discloses the use of novel materials, carrageenans, and preferably **IOTA** carrageenan, to provide gelatin-free soft capsules using a conventional process. The carrageenans are simply dissolved in a suitable medium, and then poured to form a film, which is subsequently dried (col. 4, lines 8-14). There is nothing in Paris which would teach, suggest or motivate one of ordinary skill in the art to (1) select a thickener which would react instantly with a complexing solution to form a gelled film, (2) provide a complexing solution; (3) form a film from a mass containing the thickener, or (4) contact the ungelled film with the contacting solution to instantly gel the ungelled film. Since independent claim 37 is unobvious over Paris, all the dependent claims must likewise be unobvious. Consequently, U.S. Patent 6,331,205 does not make out a *prima face* case of obviousness with respect to the presently claimed process invention, and reconsideration and withdrawal of the rejection entered under 35 USC 103(a) over Paris are respectfully requested for this reason.

Likewise, based on the description of the present invention, nothing teaches any kind of gelling agents.

Indeed this present application teaches about :

* thickening agents :

- Arabic gum and their derivatives

- lambda carrageenan

- pullulan gum and their derivatives

* dissolution medium

- water

- hydro alcoholic

* ions increasing the solubilization of lambda carrageenan :

- sodium

-potassium

* buffered solutions, alkaline or acid

* plasticizers

* surfactants : ionic, non ionic, and amphoteric

* disintegrating agents : starches and their derivatives

* complexing solutions

- saline solutions

- alcohols

* preservatives, coloring agents, opacifier agent

Therefore even if the word “comprising” is used in the application, nothing in this application teaches about any kind of gelling agents. So it seems difficult based on the description that the term “comprising” permits to understand to add something, which has never being described in the patent.

Concerning Scott applicant’s argument, the Examiner observes that one cannot show non-obviousness by attacking references individually where the rejection is based on a combination of references, citing In re Keller and In re Merck & Co.. However, applicant's arguments regarding Scott are not an attack on Scott, but rather merely an exercise is determining the scope and content of the prior art, as required under John Deere, leading to a rebuttal of the Examiner's erroneous fact finding in respect of Scott.

The presently claimed invention innovation does not employ a blend of a thickening agent and a gelling agent like those of Scott to form an ungelled film.

At most, the present invention employs blends of thickening agents.

Assuming that the Examiner's statement that Scott teaches that other thickening agents can be used in place of carrageenan is correct, his conclusion does not logically follow. Scott does not disclose, and there is nothing in Scott to suggest to one of ordinary skill in the art that this substitutability extends beyond Scott's narrow purpose, that is, for the purpose of "setting" (i.e. gelling) the aqueous pullulan solution to make a hard, brittle capsule.

Scott preferably employs kappa carrageenan, which is a gelling agent known to give brittle gels. Likewise, Scott discloses an aqueous viscous composition for hard capsules. The compositions are necessarily totally different from those appropriate for soft capsules because the manufacturing processes. Simply making a gelled mass is not enough to produce soft capsules. Other parameters must be taken into account for manufacturing soft capsules, such as the thermo-reversibility of the mass, the elasticity of the films formed from the mass, et al., none of which are considered by Scott.

Thus, Scott adds nothing to Paris to teach, suggest or motivate one of ordinary skill in the art to provide a separate complexing solution, to form an ungelled film from a viscous encapsulating mass, or to contact the ungelled film with the complexing solution to instantly gel the ungelled film. Consequently, the combination of Scott and Paris does not establish a *prima facie* case of obviousness with respect to the presently claimed invention. Reconsideration and withdrawal of the rejection, as applicable to applicant's present claims, are respectfully requested for this reason.

Reconsideration and an early notice of allowance are earnestly solicited.